

traverse the restriction requirement on the grounds that unity of invention exists for the four groups of claims, pursuant to the requirements of PCT Rules 13.1 and 13.2.

Specifically, the Examiner alleged that the special technical feature linking the four claim groups is a single stage competitive inhibitor of plasmin, and that this inhibitor is disclosed by Willmott *et al.*, *Fibrinolysis*, 9:1-8 (1995). On this basis, the Examiner concluded that the prior art reads on this special technical feature, thereby depriving the claims of unity of invention. Applicants respectfully disagree with the Examiner's analysis and conclusion.

The claimed invention is directed to a "substantially pure preparation" of a single stage competitive inhibitor of plasmin. The term "substantially pure" is defined in the application as a preparation wherein at least 60% of the total material in a sample (by volume, by weight or dry weight, or by mole percent or by mole fraction) is the compound of interest. See page 20, lines 14-24.

In contrast to the claimed invention, Willmott *et al.* do not disclose a substantially purified preparation of a single stage competitive inhibitor of plasmin. As discussed at page 4, line 9 *et seq* of the application, the plasmin inhibitor preparation of Willmott *et al.*, which was considered initially to be substantially homogeneous, was found by the present inventors to comprise two (2) different plasmin inhibitors. These inhibitors, termed Textillinin I and Textillinin II, co-migrate with a molecular mass of 7 kDa, as assessed by SDS-PAGE, and constitute only about 50% of the total protein (by weight) in the parent plasmin inhibitor preparation used by Willmott *et al.*

Thus, Willmott *et al.* do not teach a substantially homogeneous preparation of a single stage plasmin inhibitor, as recited in claims 1-40 and 46 (Group I). Nor do they disclose an isolated polynucleotide encoding a single stage competitive inhibitor of plasmin, as defined in claims 41-45 (Group II). By definition, the encoded plasmin inhibitor corresponds to a substantially purified inhibitor, as defined in Group I, which means that Group II defines a "corresponding" special technical feature in accordance with PCT rule 13.2. As to claim 47 (Group III) and claim 48 (Group IV), these claims are dependent on claim 8, which itself is dependent on claim 1, defining a substantially pure preparation of a single stage competitive inhibitor of plasmin.

Accordingly, in contradistinction to the Examiner's allegations, the claims recite the same or corresponding special technical features, which are not anticipated by

Willmott *et al.* and which, therefore, satisfy the requirements of PCT Rules 13.1 and 13.2. Withdrawal of the restriction requirement, and re-joining of the claims, are respectfully requested.

II. Conclusion

An early favorable action on the merits is awaited. Should the Examiner have any questions regarding this response, the Examiner is invited to contact the undersigned by telephone.

Respectfully submitted,

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